REMARKS

The Office Action mailed February 27, 2007 has been received and reviewed. Claim 40 has been amended herein; yet, no new matter has been added. Reconsideration of the present Application in view of the amendment to claim 40 and the following remarks is respectfully requested.

Summary of Telephonic Interview

A telephonic interview was conducted on June 18, 2007 between Applicants' representatives and Examiner Skowronek. Applicants would like to thank the Examiner for taking the time to discuss the objections and rejections delineated in the Office Action. Specifically, the Applicants' representatives indicated paragraph [0043] of the Specification described an "atypical event," as recited either directly or indirectly in claims 37, 38, 46, 47, and 51 and 52. The Examiner agreed that "atypical event" is, in fact, definite and overcomes the 35 U.S.C. § 112, second paragraph, rejection of claims claims 37, 38, 46, 47, 51, and 52. Furthermore, the Examiner also agreed that the amendment provided herein to claim 40 overcomes the § 112 rejection thereto.

Additionally, differences between claims 32-52 and the cited references Kobrinski et al. (Biomedical Engineering, Vol. 31, No. 3, p. 172-174) (referred to herein as "Kobrinski") and Pathak et al. (Proceedings of the Tenth Conference on Artificial Intelligence for Applications, p. 164-170, Mar. 1994) (referred to herein as "Pathak") were discussed. In particular, the Applicants' representatives pointed out that Kobrinski does not describe receiving a request from a clinician for test results of a gene and calculating a likelihood a person has a mutated form of a gene, as recited in various claims.

Rejections based on 35 U.S.C. § 112, second paragraph

Claims 37, 38, 40, 47, 47, and 51-52 were rejected under 35 U.S.C. § 112, second paragraph, for being indefinite. The Office Action asserts that the term "atypical event" – as recited either directly or indirectly in claims 37, 38, 47, 47, and 51-52 – is not defined either in the claims or the Specification. *See Office Action*, p. 3. Applicants submit that paragraph [0043] of the Specification describes an "atypical event," rendering the §112 rejection of these claims moot. Additionally, claim 40 has been amended herein to recite "the same database." to overcome the § 112 rejection thereto.

Rejections based on 35 U.S.C. § 102(b)

Claims 32-52 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Kobrinski. Applicants respectfully traverse these rejections for the following reasons.

For a claim to be anticipated, "each and every element as set forth in the claim" must be found "either expressly or inherently described, in a single prior art reference." MPEP § 2131 (quoting *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987)). "The identical invention must be shown in as complete detail as is contained in the . . . claim." MPEP § 2131 (quoting *Richardson Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). In other words, to anticipate a claim, a reference must teach each and every element of a claim in as complete detail as the claim recites the elements.

Independent claim 32 is directed to a method for determining and presenting the likelihood a person has a mutated form of a gene. The method comprises receiving a request from a clinician for genetic test results for a gene for a person and querying a first database to determine if the person has one or more genetic test results for the gene in response to the request

by the clinician. The method further comprises obtaining the mode of inheritance for the gene if the person does not have one or more genetic test results for the gene and querying a second database to determine whether at least one family member of the person within the mode of inheritance has one or more genetic test results for the gene. The one or more genetic test results of the at least one family member are utilized to calculate a likelihood the person has a mutated form of the gene if at least one of the family members has genetic test results for the gene. The calculated likelihood the person has a mutated form of the gene is presented to the clinician. In other words, claim 32 recites receiving a request "for genetic test results of a gene for a person" and, if no genetic test results are stored in a database, inevitably presenting the clinician with a calculated likelihood the person has a mutated form of the gene.

Kobrinski fails to teach the same. Instead, Kobrinski describes a computerized system configured to exchange information between regional and interregional medical genetic consultations and centers. *See Kobrinski* at para. 1, p. 172. At best, Kobrinski discloses a system that stores medical documentation and can be configured to apply mathematical models for calculating the risk of genetic diseases. *See id.* at para. 2, 5, and 7. But it does not describe a system that: (1) receives requests for test results for a gene of a patient, and (2) automatically calculates the likelihood a person has a mutated form of the gene based on the person's mode of inheritance when no test results exist. Stated another way, claim 32 receives a request for initial information about a patient (mutated-gene test results) and automatically returns different information (the patient's likelihood of having a gene mutation) when the initial information is not located. The mathematical models described in Kobrinski merely calculate the risk of genetic disease. No mention is made of the models returning calculated risks automatically after the system of Kobrinski is prompted for test results of a mutated gene of a patient.

For at least the above reasons, Kobrinski does not describe each and every element of claim 32. Accordingly, it is submitted that the § 102(b) rejection thereto is improper, and Applicants respectfully request its withdrawal.

Independent claim 41 is directed to a computer system for determining and presenting the likelihood a person has a mutated form of a gene. The computer system comprises a receiving module for receiving a request from a clinician for genetic test results for a gene for a person and a first querying module for querying a first database to determine if the person has one or more genetic test results for the gene in response to the request by the clinician. The system further comprises an obtaining module for obtaining the mode of inheritance for the gene if the person does not have one or more genetic test results for the gene and a second querying module for querying a second database to determine whether at least one family member of the person within the mode of inheritance has one or more genetic test results for the gene. A utilizing module utilizes the one or more genetic test results of the at least one family member to calculate a likelihood the person has a mutated form of the gene if at least one of the family members has genetic test results for the gene. A presenting module presents the calculated likelihood the person has a mutated form of the gene to the clinician. In other words, claim 41 recites several modules that are configured to carry out various aspects of claim 32.

Kobrinski fails to teach the same. As previously stated, Kobrinski discloses a system that stores medical documentation and can be configured to apply mathematical models for calculating the risk of genetic diseases. *See Kobrinski* at ¶¶ 2, 5, and 7. But it does not describe both "a receiving module for receiving a request from a clinician for genetic test results for a gene of a patient" and "a presenting module for presenting the calculated likelihood the person has a mutated form of the gene to the clinician," as required by the claims of the present application. As previously stated, Kobrinski describes using mathematical models to calculate

the risk of genetic disease for a patient, but such a calculation is not automatically performed after a determination is made that the patient has no gene-mutation test results. Therefore, both the "receiving module" and the "presenting module" of claim 41 are not described in Kobrinski. Accordingly, it is submitted that the § 102(b) rejection thereto is improper, and Applicants respectfully request its withdrawal.

Independent claim 49 is directed to a method for determining and presenting the likelihood a person has a mutated form of a gene. The method comprises querying a database to determine if the person has one or more genetic test results for the gene in response to an order for a medication for a person and obtaining the mode of inheritance for the gene if the person does not have one or more genetic test results for the gene. A database is queried to determine whether at least one family member of the person within the mode of inheritance has one or more genetic test results for the gene. The one or more genetic test results of the at least one family member are utilized to calculate a likelihood the person has a mutated form of the gene if at least one of the family members has genetic test results for the gene. The calculated likelihood the person has a mutated form of the gene is presented to a clinician.

Kobrinski fails to teach the same. Instead, it describes a computerized system configured to exchange information between regional and interregional medical genetic consultations and centers. *See Kobrinski* at ¶1, p. 172. At best, Kobrinski discloses a system that stores medical documentation and can be configured to apply mathematical models for calculating the risk of genetic diseases. *See id.* at ¶¶ 2, 5, and 7. But Kobrinski does not describe a system that: (1) queries a database to determine if a person has one or more genetic test results for a gene in response to an order for medication for a person, and (2) automatically calculates the likelihood a person has a mutated form of the gene when genetic test results for the gene cannot be located. As previously stated, the mathematical models described in Kobrinski merely

calculate the risk of genetic disease. No mention is made of them returning calculated risks automatically after a search is performed for test results of a mutated gene of a patient.

For at least the above reasons, Kobrinski does not describe each and every element of claim 49. Accordingly, it is submitted that the § 102(b) rejection thereto is improper, and Applicants respectfully request its withdrawal.

Additionally, dependent claims 33-40, 42-48, 50, and 51 are also in condition for allowance based at least in part on their dependence, either directly or indirectly, from one of independent claims 32, 41, and 49. Accordingly, Applicants respectfully request withdrawal of the § 102(b) rejections thereto.

Rejections based on 35 U.S.C. § 103(a)

Claims 32-52 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Pathak et al. (Proceedings of the Tenth Conference on Artificial Intelligence for Applications)(referred to herein as "Pathak"). Additionally, claims 32-52 were also rejected under § 103(a) as being unpatenable over Coulson et al. (Methods of Information in Medicine 2001; 40; 315-322)(referred to herein as "Coulson"). Applicants respectfully traverse the above rejections for the following reasons.

To establish a *prima facie* case of obviousness, the prior-art references must teach or suggest all the claim limitations. *See* MPEP § 2143. Furthermore, the teaching or suggestion, and the reasonable expectation of success must be found in the prior art and not be based on the Applicants' disclosure. MPEP § 2143 (referencing *In re Vaeck*, 947 F.2d 488, 493 (Fed. Cir. 1991)). Additionally, there must a reasonable expectation of success. *See MPEP* § 2143. The "teaching or suggestion" to make the claimed combination and the "reasonable expectation of success" must both be found in the prior art, not in the Applicants' disclosure. MPEP § 2143 (citing *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

A. Obviousness Rejection Premised on Pathak

With respect to independent claims 32, 41, and 49, as discussed above, Pathak does not teach or suggest receiving requests for test results of a mutated gene (or orders for medication) for a patient, querying a database for such results, and, if the results do not exist, automatically calculating a likelihood the patient has a mutated gene. Nor does Pathak teach or suggest modules configured to perform all three of these functions. To the contrary, Pathak describes calculating genetic risks, which it defines as the probability that patients may either develop a genetic disorder or transmit a genetic disease to their children. *See Pathak*, Introduction, p. 164. These risks are not automatically calculated in response to a clinicians request for genetic test results for a gene for a person.

Moreover, official notice without documentary evidence is permissible only in some circumstances to support an examiner's conclusion. *See MPEP* § 2144.03 (A). "It would not be appropriate for the examiner to take official notice of facts without citing a prior art reference where the facts asserted to be well known are not capable of instant and unquestionable demonstration as being well-known." Id. (emphasis in original). "To adequately traverse such a finding, an applicant must specifically point out the supposed errors in the examiner's action, which would include stating why the noticed fact is not considered to be common knowledge or well-known in the art." MPEP § 2144.03 (C).

The Office Action took official notice without providing supporting documentation, stating querying databases for family histories upon prescription of medication "merely automates a well known process of the medical arts." *Office Action* at p. 7. The Office further stated that a clinician always determines wither conditions exist in patients through "examination, diagnostic tests in order to prescribe potential modes of treatment." *Id.* It was

further asserted that querying databases for patient records and family-history records "upon prescription of medication merely automates a well known process of the medical arts." *Id.*

While clinicians do examine patients, it is not always common knowledge for a clinician to request test results for a gene of a person (as recited in claims 32, 41, and 49). While clinicians do examine patients, it is not always common knowledge for a clinician to request test results for a gene of a person (as recited in claims 32, 41, and 49). Furthermore, it would not to be obvious to receive a request for initial information (mutated-gene test results) for a patient from a clinician and automatically return different information (the patient's likelihood of having a gene mutation) to the clinician. Returning different information to the clinician that is different from information requested by the clinician is not a well-known process in the medical arts.

Therefore, Pathak fails to teach or suggest all of the features of claims 32, 41, and 49. Accordingly, these claims are believed to be in condition for allowance, and Applicants respectfully request withdrawal of the § 103(a) rejection thereto. In addition, dependent claims 33-40, 43-48, 51, and 52 should be allowed based in part on their dependence, either directly or indirectly, from one of claims 32, 41, or 49. *See* MPEP § 2143.03; *see also, In re Fine*, 5 USPQ 2d 1596, 1600 (Fed. Cir. 1988) ("If an independent claim is nonobvious under 35 U.S.C. § 103, then any claim depending therefrom is nonobvious.").

A. Obviousness Rejection Premised on Coulson

With respect to independent claims 32, 41, and 49, Coulson does not teach or suggest receiving requests for test results of a mutated gene (or orders for medication) for a patient, querying a database for such results, and, if the results do not exist, automatically calculating a likelihood the patient has a mutated gene. Nor does Coulson teach or suggest modules configured to perform all three of these functions. To the contrary, Coulson describes a system of creating graphical family trees and assessing genetic risk of cancer. *See Coulson*,

Summary, p. 315. These risks are not automatically calculated in response to a clinicians request for genetic test results for a gene for a person. Instead, they are generated after medical-history data is entered. *See id.* at 317, § 2.1.1 and Fig. 2.

Moreover, official notice without documentary evidence is permissible only in some circumstances to support an examiner's conclusion. *See MPEP* § 2144.03 (A). "It would not be appropriate for the examiner to take official notice of facts without citing a prior art reference where the facts asserted to be well known are not capable of instant and unquestionable demonstration as being well-known." Id. (emphasis in original). "To adequately traverse such a finding, an applicant must specifically point out the supposed errors in the examiner's action, which would include stating why the noticed fact is not considered to be common knowledge or well-known in the art." MPEP § 2144.03 (C).

The Office Action took official notice without providing supporting documentation, stating querying databases for family histories upon prescription of medication "merely automates a well known process of the medical arts." *Office Action* at p. 10. The Office further stated that a clinician always determines wither conditions exist in patients through "examination, diagnostic tests in order to prescribe potential modes of treatment." Id. It was further asserted that querying databases for patient records and family-history records "upon prescription of medication merely automates a well known process of the medical arts." *Id.*

While clinicians do examine patients, it is not always common knowledge for a clinician to request test results for a gene of a person (as recited in claims 32, 41, and 49). Furthermore, it would not to be obvious to receive a request for initial information (mutated-gene test results) for a patient from a clinician and automatically return different information (the patient's likelihood of having a gene mutation) to the clinician. Returning different information

to the clinician that is different from information requested by the clinician is not a well-known process in the medical arts.

Therefore, Coulson fails to teach or suggest all of the features of claims 32, 41, and 49. Accordingly, these claims are believed to be in condition for allowance, and Applicants respectfully request withdrawal of the § 103(a) rejection thereto. In addition, dependent claims 33-40, 43-48, 51, and 52 should be allowed based in part on their dependence, either directly or indirectly, from one of claims 32, 41, or 49. *See* MPEP § 2143.03; *see also, In re Fine*, 5 USPQ 2d 1596, 1600 (Fed. Cir. 1988) ("If an independent claim is nonobvious under 35 U.S.C. § 103, then any claim depending therefrom is nonobvious.").

CONCLUSION

Applicants submit that new claims 32-52 are in condition for allowance. If any issues remain that would prevent issuance of this Application, the Examiner is urged to contact the undersigned by telephone prior to issuing a subsequent action. The Commissioner is hereby authorized to charge any additional amount required (or credit any overpayment) to Deposit Account No. 19-2112.

Respectfully submitted,

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